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EXAMINER	
PAULS, JOHN A	

ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,553	SHAH, RAJESH NAVANITAL	
	Examiner	Art Unit	
	JOHN A. PAULS	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the communication filed on 12 November, 2009.

2. Claims 1 – 31 and 38 have been amended.

3. Claims 32 – 37 and 39 – 47 have been cancelled.

4. Claims 1 – 31 and 38 are currently pending and have been examined.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the limitation "*the patient*" There is insufficient antecedent basis for this limitation in the claim. The term "*the patient*" is not recited in either claim 11 or claim 1.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 – 11, 13 – 20, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Thangaraj et al. (WO 01/093160 A1).

CLAIM 1

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *at least one database for storing information relating to at least one clinical trial;* (see at least Thangaraj page 2 line 11 - 19);
- *one or more processors configured to:*
    - *interface with one or more client devices of one or more users, at least one of the one or more users having an assigned role in the at least one clinical trial;* (see at least Thangaraj page 2 line 11 – 19, page 3 line 18 to page 4 line 6, page 4 line 13 – 19 and page 9 line 32 to page 10 line 7 and Figure 1);
    - *receive, from a user, protocol design information relating to design* (clinical trial setup) *of a protocol for the at least one clinical trial;* (see at least Thangaraj page 2 line 11 – 19 and line 31 – 34, page 12 line 24 – 34, page 19 line 27 – 32 and page 25 line 23 – 33);
    - *interface with one or more third party standards databases to acquire predefined standards information relevant to the protocol for the at least one clinical trial;* (see at least Thangaraj page 5 line 13 – 19, page 9 line 25 – 30, page 9 line 32 to page 10 line 7, page 11 line 15 - 19, page 12 line 24 - 34, page 19 line 27 - 32, page 20 line 25 - 31, page 22 line 5 - 8, page 24 line 5 - 20 and page 25 line 5 – 15);
    - *formulate the protocol using at least the design information and the standards information;* (see at least Thangaraj page 2 line 11 – 19 and line 31 – 34, page 12 line 24 - 34, page 19 line 27 - 32 and page 25 line 23 – 33);

- *store the formulated protocol in the at least one database;* (see at least Thangaraj page 2 line 11 – 19, page 10 line 29 – 35, page 11 line 26 – 33, page 16 line 17 – 24 and page 18 line 7 - 17);
- *receive subject information relating to one or more subjects of the at least one clinical trial;* (see at least Thangaraj page 20 line 10 - 15);
- *store the subject information in the at least one database;* (see at least Thangaraj page 2 line 11 – 19, page 10 line 29 – 35, page 11 line 26 – 33, page 16 line 17 – 24 and page 18 line 7 - 17);
- *receive clinical data regarding the one or more subjects relevant to the at least one clinical trial;* (see at least Thangaraj page 20 line 32 to page 22 line 8);
- *store the clinical data in the at least one database;* (see at least Thangaraj page 2 line 11 – 19, page 10 line 29 – 35, page 11 line 26 – 33, page 16 line 17 – 24 and page 18 line 7 - 17);
- *formulate at least one clinical result based on at least the protocol, the subject data, and the clinical data;* (see at least Thangaraj page 22 line 9 - 12);
- *store the at least one clinical result in the at least one database;* (see at least Thangaraj page 2 line 11 – 19, page 10 line 29 – 35, page 11 line 26 – 33, page 16 line 17 – 24 and page 18 line 7 - 17);
- *provide information stored in the at least one database to one or more of the one or more users via the one or more client devices, wherein access for a given user from the one or more users is gated based on the given user's assigned role,* (see at least

Thangaraj page 2 line 11 – 19, page 3 line 18 to page 4 line 6, page 4 line 13 – 19, page 9 line 32 to page 10 line 7 and page 10 line 29 to page 11 line 7).

CLAIMS 2 – 7, 9 and 11

Thangaraj as shown discloses the limitations shown above relative to Claim 1. Thangaraj also discloses the following limitations:

- *one or more client devices include a web client that interfaces with the one or more processors via a web connection, the web client comprising one of a computer, a cellular telephone, or a personal data assistant;* (see at least Thangaraj page 4 line 13 – 19 and page 15 line 30 to page 16 line 13);
- *one or more client devices include at least one client device that interfaces with the one or more processors via a connection other than a web connection, the at least one client device comprising one of a computer, a cellular telephone, or a personal data assistant;* (see at least Thangaraj page 4 line 7 – 19, page 10 line 15 – 20 and page 15 line 30 to page 16 line 13);
- *the one or more users include one or more of a sponsor, a regulator, an investigator, a site, a patient, or a monitor;* (see at least Thangaraj page 3 line 10 – 17 and page 9 line 32 to page 10 line 7);
- *compare received clinical data with one or more predefined data integrity standards, wherein all information stored in the at least one database is stored according to one or more predefined security and privacy standards;* (see at least Thangaraj page 2 line 31 – 32; page 3 line 5 – 8 and line 24 – 30; page 5 line 13 - 19 and page 12 line 24 – 34);

- *wherein the one or more processors configured to provide information stored in the at least one database to one or more users via the one or more client devices further comprise one or more processors configured to provide user-defined password protected access to the at least one database according to the predefined security and privacy standards;* (see at least Thangaraj page 3 line 5 - 8, page 3 line 31 to page 4 line 6, page 11 line 26 - 33, page 12 line 24 - 34 and page 13 line 10 - 33);
- *generate one or more reports for filing with a regulatory entity using at least the protocol, the subject data and the at least one clinical result;* (see at least Thangaraj page 5 line 13 – 19, page 9 line 25 – 30, page 11 line 15 – 19, page 12 line 24 – 34, page 20 line 21 – 24 and page 22 line 5 - 8);
- *predefined data integrity standards include one or more of the Health Level 7, 21 CFR Part 11, Health Insurance Portability and Accountability Act (1996), or American Society for Testing and Materials requirements;* (see at least Thangaraj page 9 line 25 – 30, page 20 line 25 – 31 and page 25 line 5 - 15);
- *the one or more processors are further configured to receive potential candidate information, compare the potential candidate information with candidate acceptance rules, and identify one or more of the one or more subjects based on the comparison;* (see at least Thangaraj page 20 line 10 – 15);
- *the formulated protocol includes one or more controlled documents detailing implementation of the protocol and wherein the one or more processors are further configured to receive change information relating to a change in the formulated*

protocol, modify one or more of the one or more controlled documents according to the change information; (see at least Thangaraj page 19 line 27 – 32 and page 20 line 25 - 31);

CLAIMS 13 - 20

Thangaraj as shown discloses the limitations shown above relative to Claim 1. Thangaraj also discloses the following limitations:

- *clinical trial data includes adverse event data relating to one or more adverse events relevant to the at least one clinical trial, and wherein the one or more processors as further configured to generate one or more reports relating to the adverse event data in compliance with one or more predetermined adverse event reporting requirements;* (see at least Thangaraj page 22 line 5 – 8);
- *one or more processors are further configured to provide information from the at least one database to one or more entities to comply with one or more predetermined monitoring or auditing requirements;* (see at least Thangaraj page 22 line 5 - 8);
- *one or more processors are further configured to generate one or more case report forms in one or more of paper or electronic forms;* (see at least Thangaraj page 5 line 13 – 19);
- *one or more processors are further configured to generate interim and final clinical trial status reports;* (see at least Thangaraj page 12 line 24 – 34, page 19 line 13 – 26, page 20 line 21 – 24 and page 25 line 9 - 10);
- *clinical data includes drug distribution information relating to drugs dispensed to one or more subjects participating in the at least one clinical trial and wherein the one or more*

processors are further configured to generate one or more reports reflecting part or all of the drug distribution information according to one or more predetermined drug distribution rules; (see at least Thangaraj page 20 line 25 – 31);

- *one or more processors are further configured to enable external application to communicate with the system and facilitate import and export of data in XML format to and from the patient records database;* (see at least Thangaraj page 17 line 20 to page 18 line 17 and page 22 line 18 – 32);
- the one or more processors configured to enable external application to communicate with the system are further configured to allow mobile devices to enter and retrieve data from the at least one database as one or more clients; (see at least Thangaraj page 4 line 13 – 19, page 15 line 30 to page 16 line 13 and page 17 line 20 – 32);

CLAIM 21

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *identifying one or more reporting requirements for a specific stakeholder associated with the clinical trial;* (see at least Thangaraj page 20 line 21 – 24, page 22 line 5 – 8 and page 25 line 5 - 8);
- *extracting data from the at least one database related to the clinical trial based on the reporting requirements for the stakeholder;* (see at least Thangaraj page 10 line 8 – 14 and page 25 line 5 - 8);
- *validating the extracted data against one or more predefined regulations or standards;* (see at least Thangaraj page 11 line 15 – 19 and page 25 line 5 - 8);

- *generating one or more clinical results using the extracted data based on a role associated with the specific stakeholder;* (see at least Thangaraj page 13 line 14 – 33, page 22 line 5 – 8 and page 25 line 5 - 8);
- *displaying the information to the specific stakeholder;* (see at least Thangaraj page 13 line 14 – 33 and page 22 line 5 - 8).

CLAIM 22

Thangaraj as shown discloses the limitations shown above relative to Claim 21. Thangaraj also discloses the following limitations:

- *the role associated with the specific stakeholder comprises on of a sponsor, a regulator, an investigator, a site, a patient, or a monitor*; (see at least Thangaraj page 3 line 10 – 17 and page 9 line 32 to page 10 line 7).

CLAIM 23

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *receiving event information relating to performance of an event defined in a protocol of a clinical trial;* (see at least Thangaraj page 5 line 13 - 19);
- *validating the event information using one or more predefined standards;* (see at least Thangaraj page 9 line 25 – 30; page 11 line 15 – 19 and page 19 line 27 - 32);
- *determining, according to one or more predefined alert rules, whether at least one stakeholder associated with the clinical trial is to be alerted to the event;* (see at least Thangaraj page 22 line 5 – 8 and page 23 line 28 - 34);

- *alerting the at least one stakeholder of the event;* (see at least Thangaraj page 22 line 5 – 8 and page 23 line 28 - 34).

CLAIM 38

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *locking a database storing information regarding the clinical trial after all information regarding subjects enrolled in the clinical trial has been entered;* (see at least Thangaraj page 23 line 28 - 34);
- *notifying at least one stakeholder associated with the clinical trial of completion of the clinical trial when the database has been locked;* (see at least Thangaraj page 23 line 28 - 34);
- *generating a final clinical study report using the information stored in the database;* (see at least Thangaraj page 11 line 15 – 19; page 11 line 26 – 33 and page 12 line 24 - 34).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thangaraj et al. (WO 01/093160 A1) and in further view of DeVries et al. (WO 02/044868 A3).

Thangaraj as shown discloses the limitations shown above relative to Claim 1. Thangaraj may or may not specifically disclose the following limitations, however, DeVries does:

- *a dictionary and standards component, wherein the dictionary and standards component enables interfaces between the system and relevant dictionaries and standards comprising one or more of common data elements, common toxicity criteria, MedDRA codes, ICD9/10 codes, IMT codes, and Common Data Interchange Standards Consortium;* (see at least DeVries page 14 line 9 – 15);
- *the one or more processors are configured to receive information from external electronic medical records as clinical data*; (see at least DeVries page 26 line 22 – 30).

DeVries discloses clinical trial management system which includes reusable database of common elements and connecting to other electronic medical records. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the clinical trial management system of Thangaraj so as to have included reusable database of common elements and connecting to other electronic medical records, in accordance with the teaching of DeVries, in order to increase the efficacy of a clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thangaraj et al. (WO 01/093160 A1) and in further view of Kapp (US PGPUB 2002/0010595 A1).

Thangaraj as shown discloses the limitations shown above relative to Claim 1. Thangaraj may or may not specifically disclose the following limitations, however, Kapp does:

- *the one or more processors are further configured to assign codes from a predetermined set of codes to one or more of diagnosis information, treatment information, disease information, or toxicity data present in the subject data, the clinical data, or the clinical results;* (see at least Kapp paragraph 0046 and 0056).

Kapp discloses a medication management system which includes using ICD-9 codes for entry of diagnosis information in a clinical trial. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the clinical trial management system of Thangaraj so as to have included using ICD-9 codes for entry of diagnosis information in a clinical trial, in accordance with the teaching of Kapp, in order to standardize the information collection of data during a clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thangaraj et al. (WO 01/093160 A1) and in further view of Buonocore et al. (US PGPUB 2004/0010418 A1).

Thangaraj as shown discloses the limitations shown above relative to Claim 11. Thangaraj may or may not specifically disclose the following limitations, however, Buonocore does:

- *schedule one or more clinical trial related visits for one or more subjects and wherein the received clinical data includes information relating to the patient captured at the one or more scheduled clinical trial related visits;* (see at least Buonocore paragraph 0009, 0016, 0019, 0028, 0029 and 0031).

Buonocore discloses clinical trial management system which includes patient scheduling capability. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the clinical trial management system of Thangaraj so as to have included patient scheduling capability, in accordance with the teaching of Buonocore, in order to increase the efficacy of a clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

14. Claims 24 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buonocore et al. (US PGPUB 2004/0010418 A1).

CLAIM 24

Buonocore as shown discloses a clinical trial management system with the following limitations:

- *enrolling one or more subjects in a clinical trial based on exclusion and inclusion criteria of a protocol of the clinical trial;* (see at least Buonocore paragraph 0026 and 0028);
- *generating a schedule of subject visits for at least one of the one or more enrolled subjects based the protocol;* (see at least Buonocore paragraph 0009);

- *providing alerts that the enrolled subject should be sent reminders in advance of subsequent visits of the subject;* (see at least Buonocore paragraph 0017);
- *providing one or more alerts regarding reminders to be sent to the at least one subject in advance of scheduled subject visits;* (see at least Buonocore paragraph 0011, 0016, 0029 and 0031);
- *generating a checklist of items related to a scheduled visit of the at least on subject;* (see at least Buonocore paragraph 0040);
- *documenting items from the checklist that are completed or not completed;* (see at least Buonocore paragraph 0040 and 0045);
- *documenting scheduled visits not attended by the at least one subject;* (see at least Buonocore paragraph 0045);

Buonocore may or may not specifically disclose the following limitations:

- *dropping the at least one subject if a number of visits not attended exceeds a predetermined threshold;*
- *notifying the at least one subject when the number of visits not attended exceeds the threshold.*

However, the system of Buonocore does disclose

- a request for response from the clinical trial participant that tracks requests not completed and tracks missed events related to the clinical trial and notifies the subject and the investigator for the purpose of retaining or correcting the deviation by a clinical trial participant.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify Buonocore to include notifying the subject and dropping them from the trial if the number of requests not completed exceeds a predetermined threshold in order to maintain the value of the clinical trial, since doing so could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 25 and 26

Buonocore as shown discloses the limitations above as they relate to Claim 24. Buonocore also discloses the following limitations:

- *the scheduled subject visits comprise one or more of an office visit, laboratory tests, imaging tests, procedures, or preparation for procedures;* (see at least Buonocore paragraph 0030 and 0031);
- *the checklist of items include one or more of prompting a principal investigator review and signature, generating patient instructions, generating a coordinator checklist, checking laboratory results, checking pathology results, checking microbiology results, or checking study reports;* (see at least Buonocore paragraph 0011 and 0031).

CLAIM 27

Buonocore as shown discloses the limitations above as they relate to Claim 24. Buonocore may or may not specifically disclose the following limitations:

- *the predetermined threshold of visits not attended comprises three visits.*

While Buonocore et al. fails to disclose the particular recited three visits, it would nevertheless have been obvious to one of ordinary skill in the art, at the time of the invention, to have further

modified the method of Buonocore et al. so as to have included a threshold of three visits including as recited in the instant claims, merely as a matter of design choice, in order to maintain the value of the clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIM 28

Buonocore as shown discloses the limitations above as they relate to Claim 24. Buonocore may or may not specifically disclose the following limitations:

- *the notifying the at least one subject comprises sending a certified letter to the at least one subject.*

However, Examiner takes **Official Notice** that it is old and well known in the art to notify a subject of an action by certified letter. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify Buonocore with the **Official Notice** taken so that participant who fail to comply with the trial protocol be dropped after missing a threshold of visits and be notified of that action by certified letter in order to increase the efficacy of a clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

The Examiner would like to note the requirements for traversing official notice from MPEP § 2144.03:

> To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed

fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b).

If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate [emphasis added].

Because Applicant has not specifically pointed out any errors in the Examiner's action, the officially noticed facts in the 12 May, 2009 Office Action are deemed admitted prior art.

CLAIM 29

Buonocore as shown discloses a clinical trial management system with the following limitations:

- *receiving a protocol for a clinical trial;* (see at least Buonocore paragraph 0009);
- *formulating a schedule of visits for at least one subject enrolled in the clinical trial;* (see at least Buonocore paragraph 0029);
- *modifying the schedule of subject visits to be consistent with the clinical trial protocol and predefined rules of informed consent;* (see at least Buonocore paragraph 0008, 0009 and 0029);
- *collecting subject information according to one or more predefined standards;* (see at least Buonocore paragraph 0008 and 0028);

- *checking the collected subject information against inclusion and exclusion criteria of one or more predetermined business logic rules;* (see at least Buonocore paragraph 0008 and 0026);
- *for at least one subject visit from the schedule of visits, sending a reminder to the at least one patient regarding the at least one subject visit;* (see at least Buonocore paragraph 0029).

Buonocore as shown may or may not specifically disclose the following limitations:

- *dropping the at least one subject from the clinical trial if a number of visits not attended exceeds a predetermined threshold;*
- *notifying the at least one subject when the number of visits not attended exceeds the predetermined threshold.*

However, the system of Buonocore does disclose

- a request for response from the clinical trial participant that tracks requests not completed and tracks missed events related to the clinical trial and notifies the investigator for the purpose of retaining or correcting the deviation by a clinical trial participant.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify Buonocore to include notifying the subject and dropping them from the trial if the number of requests not completed exceeds a predetermined threshold in order to maintain the value of the clinical trial, since doing so could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIM 30

Buonocore as shown discloses a clinical trial management system with the following limitations:

- *generating a schedule of subject visits for at least one subject enrolled in a clinical trial;* (see at least Buonocore paragraph 0009);
- *notifying, at a beginning of at least one subject visit from the generated schedule of subject visits, at least one stakeholder associated with the clinical trial that the at least one subject visit has begun;* (see at least Buonocore paragraph 0029 - 0031);
- *if the at least one subject has failed to attend at least one subject visit from the generated schedule of subject visits, alerting the at least one stakeholder that the at least one subject has not attended the at least one subject visit;* (see at least Buonocore paragraph 0045 and 0046).

Buonocore as shown may or may not specifically disclose the following limitations:

- *dropping the at least one subject from the clinical trial if a number of visits not attended exceeds a predetermined threshold;*
- *notifying the at least one stakeholder if the at least one subject is dropped for exceeding the predetermined threshold.*

However, the system of Buonocore does disclose

- a request for response from the clinical trial participant that tracks requests not completed and tracks missed events related to the clinical trial and notifies the investigator for the purpose of retaining or correcting the deviation by a clinical trial participant.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify Buonocore to include notifying the subject and dropping them from the trial if the number of requests not completed exceeds a predetermined threshold in order to maintain the value of the clinical trial, since doing so could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

15. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buonocore et al. (US PGPUB 2004/0010418 A1) and in further view of Thangaraj et al. (WO 01/093160 A1).

CLAIM 31

Buonocore as shown discloses the limitations shown above relative to Claim 30. Buonocore may or may not specifically disclose the following limitations, however, Thangaraj does:

- *the stakeholder comprises one of sponsor, regulator, investigator, site, patient, or monitor;* (see at least Thangaraj page 3 line 5 – 8 and page 9 line 32 to page 10 line 7).

Thangaraj discloses clinical trial management system which includes a stakeholder definition. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the clinical trial management system of Buonocore so as to have included a stakeholder definition, in accordance with the teaching of Thangaraj, in order to clarify the roles of clinical trial stakeholders, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Response to Arguments

Applicant's arguments filed 12 November, 2009 have been fully considered but they are not persuasive.

Applicant argues that Thangaraj fails to disclose an interface to a third party standards database used to formulate a clinical trial protocol. Examiner respectfully disagrees. Thangaraj in the cited passages and Figures discloses a clinical trial management system that includes trial design and connections to external databases including the FDA.

Applicant argues that Thangaraj fails to disclose extracting data based on the reporting requirements of a stakeholder. Examiner respectfully disagrees. Thangaraj in the cited passages discloses a clinical trial management system that tailors the reports based on the role of the clinical trial participant.

Applicant argues that Thangaraj fails to disclose notifying a stakeholder when the clinical trial database has been locked. Examiner respectfully disagrees. Thangaraj in the cited passages and Figures discloses a clinical trial management system that notifies trial participants when the database has been locked.

Applicant argues that Buonocore fails to disclose documenting items that have been completed or not completed. Examiner respectfully disagrees. Buonocore discloses a clinical trial management system that notifies an investigator when an item is not completed. The lack of such notification implies that the item has been completed. Applicant argues that Examiner has used impermissible hindsight in rejecting certain features not specifically disclosed in Buonocore, specifically dropping a subject who misses a predetermined number of visits and then notifying them that they have been dropped from the trial. In response to applicant's argument that the

examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It would be obvious to one of ordinary skill in the art at the time of the invention that a subject who was not participating at a level necessary to complete the clinical trial would be dropped and notified of that action.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **(571) 270-5557.** The Examiner can normally be reached on Monday to Friday 7:30 to 5:00 4/5/9.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington, D.C. 20231

or faxed to (571) 273-**8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

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/J. A. P./
Examiner, Art Unit 3686
Date: 5 January, 2010

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686